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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,989	10/30/2001	Shunichi Shiozawa	2001-1298A	2860

513 7590 11/27/2002

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,989	SHIOZAWA ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8 and 10-18* is/are pending in the application.

4a) Of the above claim(s) *4-8,10,11 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. This action is in response to Paper No. 12, filed August 30, 2002. Applicants arguments and amendments presented in the response of Paper No. 12 have been fully considered but are not persuasive to overcome all grounds of rejection. Any rejections not reiterated herein are hereby withdrawn. This action is made final.

2. This application contains claims 4-8, 10, 11, and 15-18 drawn to an invention nonelected without traverse in Paper No. 9. In the response of Paper No. 12, Applicants state that non-elected method claims 7 and 15-18 should be rejoined upon the allowance of the product claims. However, all present product claims are **not** allowable.

3. Claims 3 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to DNA fragments comprising nucleotides 2693-2702 of SEQ ID NO: 1. The specification teaches a cDNA that differs from the wild-type Db1 cDNA (as defined by Ron et al. EMBO Journal. 1998. 7: 2465-2473) in that nucleotides 2698-2952 of the wild-type cDNA are deleted and nucleotides 1-61 of SEQ ID NO: 2 are substituted therefor. The claims as broadly written include nucleic acids in which sequences are present flanking the 10 mer nucleotides 2693-2702 of SEQ ID NO: 1. Accordingly, the broadest reasonable interpretation of the claims indicates that the claims are inclusive of genes and genomic sequences. However, the specification does not teach any full length genes or genomic sequences. In *The Regents of the*

University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, the prior art teaches the wild-type Db1 cDNA and the specification teaches a single variant of this cDNA. The specification and prior art do not teach Db1 genomic sequences, such as intronic sequences or 3' or 5' untranslated sequences. In addition, the claims do not provide any meaningful limitations to define the structure or the function of the "cDNA of the disease gene". The claims include genomic and cDNAs comprising nucleotides 2693-2702 of SEQ ID NO: 1 wherein the sequences flanking nucleotides 2693-2702 of SEQ ID NO: 1 are not defined and the functional activity of the genomic and cDNA is not provided. However , the specification discloses only one Db1 variant comprising nucleotides 2693-2702 of SEQ ID NO: 1. The specification does not disclose any additional Db1 variants or other genes comprising nucleotides 2693-2702 of SEQ ID NO: 1. It is

then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing applicants were in possession of a cDNA that differs from the wild-type Db1 cDNA in that nucleotides 2698-2952 of the wild-type cDNA are deleted and nucleotides 1-61 of original SEQ ID NO: 2 are substituted therefor, a representative number of species encompassed by the claimed genus of polynucleotides are not disclosed in the specification . The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of full length Db1 disease genes, genomic Db1 nucleic acids, variants of a disease gene or cDNA defined only in terms of nucleotide positions 19/20-274 of SEQ ID NO: 1 or nucleotides 2693-2702 of SEQ ID NO: 1. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 12, Applicants traversed this rejection by stating that the claims have been amended to be limited to new SEQ ID NO: 1 and part(s) thereof. Applicants note that the office action on April 24, 2002 "agrees with such a conclusion." This

statement is not correct. The office action of April 24, 2002 did **not** state that Applicants originally filed specification provides basis for all nucleic acids comprising nucleotides 2693-2702 of newly added SEQ ID NO: 1. The specification as originally filed disclosed a cDNA that differs from the wild-type Db1 cDNA (as defined by Ron et al. EMBO Journal. 1998. 7: 2465-2473) in that nucleotides 2698-2952 of the wild-type cDNA are deleted and nucleotides 1-61 of the original SEQ ID NO: 2 are substituted therefor. Furthermore, the originally filed specification described a nucleic acid molecule **consisting of** the previously claimed SEQ ID NO: 3. However, the specification does not disclose and adequately describe the genus of any nucleic acid molecule comprising nucleotides 2693-2702 of amended SEQ ID NO: 1. The specification and claims do not define the flanking sequence nor do they define the functional activity of such a nucleic acid molecule. Accordingly, the broadly claimed genus of nucleic acids are not adequately defined in terms of structure or function and a representative number of species within the claimed genus have not been adequately described.

4. THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE SPECIFICATION AND CLAIMS:

The amendment filed August 30, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The specification as originally filed does not provide basis for the amendments to SEQ ID NO: 1, 2, 5 and 6. The specification as originally filed disclosed a cDNA that differs from the wild-type Db1 cDNA (as defined by Ron et al. EMBO Journal. 1998. 7: 2465-2473) in that nucleotides 2698-2952 of the wild-type cDNA are deleted and nucleotides 1-61 of the original SEQ ID NO: 2 are substituted therefor. Applicants state that the protooncogene Db1 cDNA is known and refer to "GenBank Accession No. X12556 enclosed herewith." However, the originally filed specification did not incorporate by reference this wildtype sequence. The specification described a specific variant of the Db1 gene (defined on page 4 of the specification). Disclosure of the variant sequence does not provide basis for the concept of including the wild-type nucleic acid and amino acid sequence in the specification (i.e., SEQ ID NO: 5 and 6). Secondly, in the response of Paper No. 12, Applicants explanation of how they have extensively modified the sequence listing is unclear. There does not appear to be support in the specification as originally filed for the amendments to SEQ ID NO: 1 and 2. The specification states that the sequence of the 241st base in SEQ ID NO: 1 is linked to the downstream side of the 18th base. Yet the new SEQ ID NO: 1 appears to link the 18th base to the 242nd base. The specification as originally filed does not provide support for this amendment.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. Claims 1, 3 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed in paragraph 4 above, the specification as originally filed does not provide basis for SEQ ID NO: 1 as amended. While the specification states that the sequence of the 241st base in SEQ ID NO: 1 is linked to the downstream side of the 18th base, the new SEQ ID NO: 1 appears to link the 18th base to the 242nd base. The specification as originally filed does not provide support for this amendment. Furthermore, while the specification as originally filed provides basis for the fragments having the sequence of SEQ ID NO: 1 and 2 (which are subfragments of the present SEQ ID NO: 1 consisting of 274 and 61 nucleotides, respectively), the specification as originally filed does not provide basis for the additional fragments encompassed by any DNA fragments "which comprise the base sequence of a part of SEQ ID NO: 1, and necessarily contains the base sequence from 2693rd to 2702nd of SEQ ID NO: 1." That is, present SEQ ID NO: 1 consists of 3429 nucleotides and the specification does not provide support for the additional DNA fragments comprising the fragment from 2693-2702 of amended SEQ ID NO: 1.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gewirtz (U.S. Patent No. 5,612,212).

Gewirtz teaches a protooncogene which comprises the sequence of nucleotides 2693-2702 of amended SEQ ID NO: 1. In particular, SEQ ID NO: 7 of Gewirtz contains nucleotides 5-14 which are identical to nucleotides 2693-2702 of amended SEQ ID NO: 1. Accordingly, the claimed DNA fragments are anticipated by the nucleic acids of Gewirtz. .

RESPONSE TO ARGUMENTS:

In the response of Paper No. 12, Applicants traversed this rejection by stating that the claims have been amended to recite a "DNA fragment which **comprises** the base sequence of **a part of** SEQ ID NO: 1. Applicants assert that the claims require an additional part of SEQ ID NO: 1 not present in Gewirtz in addition to nucleotides 2693-2702. However, the claims do not require such a limitation. The claims require only that the DNA fragment necessarily comprises a portion of SEQ ID NO: 1 and this portion must include nucleotides 2693-2702 of amended SEQ ID NO: 1. Gewirtz teaches a nucleic acid which comprises nucleotides 2693-2702 of amended SEQ ID NO: 1 and thereby anticipates the claimed invention. To clarify, the claims do **not** require that the DNA fragment includes sequences of SEQ ID NO: 1 which flank nucleotides 2693-2702 of SEQ ID NO: 1.

7. Claims 1, 3, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Kamai et al (Arthritis and Rheumatism (Sept 1999) 42(9 supplement) page S392; for meeting held Tuesday November 16, 1999).

Kamai et al disclose an isolated Db1 mutant nucleic acid, RA3, which differs from wild-type Db1 in that it contains a 223 bp deletion at the 3' end. In the absence of evidence to the contrary, the mutant Db1 nucleic disclosed by Kamai is considered to be identical to the presently claimed "disease gene for rheumatoid arthritis" and it is a characteristic of the mutant Db1 nucleic acid of Kamai that it comprises nucleotides 2693-2702 of amended SEQ ID NO: 1.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 12, Applicants state that the rejection has been obviated because Applicants have filed a certified translation of their priority document. However, the priority document does not provide basis for the presently claimed cDNA of SEQ ID NO: 1 or the claimed fragment thereof. Accordingly, Applicants are not entitled to the filing date of March 20, 1999 for the presently claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER

November 26, 2002